Congress of the United States

Washington, DC 20515

September 29, 2022

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We appreciate the steps the Food and Drug Administration (FDA) has taken to accelerate the development and authorization of COVID-19 medical countermeasures early in the pandemic, including creating the Coronavirus Treatment Acceleration Program (CTAP). However, it is now clear that COVID-19 variants like Delta and Omicron, and subvariants like Omicron BA.4 and Omicron BA.5, have rendered previous vaccines less effective in preventing infection and have left several authorized therapeutics ineffective. As a result, there are limited options to prevent and treat current and future COVID-19 variants.

We urge the FDA to ensure that the availability of multiple therapeutic (prevention and treatment) options for patients keeps pace with the emergence of COVID-19 variants. Hospitals are still seeing a high number of COVID-19 cases, and many communities are experiencing medium and high community levels of COVID-19.[1] Due to the unpredictable nature of future variants, a diverse portfolio of products for both prevention and treatment against a wide range of variants is needed.

We concur with the July 20 letter to the FDA signed by 16 diverse patient organizations, which expressed concerns that "millions of vulnerable Americans who have limited options for protection against COVID-19 are going to remain isolated" and urged "the FDA to continue its extraordinary commitment to ensuring that we have a variety of COVID-19 treatment and prevention options in place to address new variants as they arise and that broaden protections for everyone, but particularly the most vulnerable among us."

COVID-19 has disproportionately impacted racial and ethnic minority populations. Age-standardized data show that Hispanic, Black, and Alaskan Native people are at 1.5x greater risk of COVID-19 infection than their White counterparts.[2] Earlier this year, even as case rates began to fall sharply across the U.S., the hospitalization rate for Black Americans was 65 per 100,000 – more than 2x the overall rate.[3] Because there is no single solution for all variants and all patients, multiple tools are needed in America's public health arsenal to effectively prevent, treat, and curb the spread of COVID-19.

For instance, antibody therapies are a critically important component of the broad toolkit as they have the potential to both treat and prevent COVID-19. This is especially crucial for the seven million immunocompromised patients[4] in the U.S., such as cancer and transplant patients who are unable to mount a

[1] COVID Data Tracker Weekly Review, May 20, 2022, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.
[2] Kaiser Family Foundation, COVID-19 Cases and Deaths by Race/Ethnicity: Current Data and Changes Over Time, February 22, 2022, https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-cases-and-deaths-by-race-ethnicity-current-data-and-changes-over-time/
[3] Black Coalition Against COVID, The State of Black America and COVID-19, A Two Year Assessment, May 31, 2022, 2022-Report-State-of-Black-America-and-COVID-19-A-Two-Year-Assessment-3292022.pdf
[4] ACIP Evidence to Recommendations for Use of an Additional COVID-19 Vaccine Dose in Immunocompromised People, https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-immunocompromised-etr.html.

sufficient antibody response to vaccines. Antibodies also have low potential for interactions with other important medications these individuals may be taking. Maintaining a library of multiple antibody therapies that can prevent and treat COVID-19 will increase the nation's ability to respond quickly to new variants and prevent increases in hospitalizations and deaths.

Our concern is that new variants are becoming dominant faster than current FDA emergency use authorization (EUA) processes and product deployment. We urge FDA to consider how the research, authorization, and approval processes can be streamlined and improved to support additional medical countermeasures for new COVID-19 variants. In particular, we ask FDA to:

- Clarify and consistently apply clinical standards for determining the efficacy of products as emerging variants are identified.
- Clarify how applications for COVID-19 therapeutics are being prioritized for review.
- Consider reducing the need for large safety databases at different doses for therapeutics with well-established safety profiles.
- Consider how flexibilities developed by the Center for Biologics Evaluation and Research for evaluating COVID-19 vaccines can be applied to the evaluation process for COVID-19 therapeutics at the Center for Drug Evaluation and Research.

We look forward to hearing from you on how you plan for FDA processes to keep pace with the emergence of COVID-19 variants.

Sincerely,

A. Donald McEachin
Member of Congress

John Joyce, M.D.
Member of Congress

Jake Auchincloss
Member of Congress

Neal P. Dunn, M.D.
Member of Congress

Tom O'Halleran
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Derek Kilmer
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Kim Schrier, M.D.
Member of Congress

Brett Guthrie
Member of Congress

Andrew R. Garbarino
Member of Congress

H. Morgan Griffith
Member of Congress

Mariannette Miller-Meeks, M.D.
Member of Congress

Fred Upton
Member of Congress